IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS CORPORATION

Plaintiff,

v.

Civil Action No. _____

APOTEX INC., APOTEX CORP., BIONPHARMA INC., EMCURE PHARMACEUTICALS, HERITAGE PHARMACEUTICALS INC., EZRA VENTURES, LLC, GLENMARK PHARMACEUTICALS INC., USA, GLENMARK PHARMACEUTICALS LIMITED, HEC PHARM CO., LTD., HEC PHARM USA INC., HETERO USA INC., HETERO LABS LIMITED UNIT-V, HETERO LABS LIMITED, PRINSTON PHARMACEUTICAL INC., STRIDES GLOBAL PHARMA PRIVATE LIMITED, STRIDES PHARMA, INC., ZYDUS PHARMACEUTICALS (USA) INC., and CADILA HEALTHCARE LIMITED

Defendants.

COMPLAINT

Novartis Pharmaceuticals Corporation ("Novartis") by its attorneys hereby alleges as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code and for declaratory judgment pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201, *et seq*. This action relates to Abbreviated New Drug Applications ("ANDAs") filed by the above-named defendants with the U.S. Food and Drug Administration ("FDA") for approval to engage in the commercial manufacture, use, or sale of Fingolimod 0.5 mg capsules, generic versions of Novartis's GILENYA® Capsules, 0.5 mg, prior to expiration of U.S. Patent No. 10,543,179 ("the '179 patent").

PARTIES

A. Novartis

2. Novartis Pharmaceuticals Corporation is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business in East Hanover, New Jersey.

B. The Generic Defendants

a) Apotex Inc.; Apotex Corp.

3. Upon information and belief, Defendant Apotex Inc. is a corporation organized and existing under the laws of Canada, having a principal place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9.

4. Upon information and belief, Apotex Inc. itself, and through its wholly-owned subsidiary and agent, Apotex Corp., develops, manufactures, and/or distributes generic drug products for marketing, sale, and/or use throughout the United States, including in this judicial district.

5. Upon information and belief, Defendant Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

6. Upon information and belief, Apotex Inc. is in the business of, among other things, developing, manufacturing, and selling generic versions of branded pharmaceutical products for the U.S. market. Upon information and belief, Apotex Corp. is a wholly-owned subsidiary of Apotex Inc. and is controlled and/or dominated by Apotex Inc. Upon information and belief, Apotex Corp. develops, manufactures, and/or distributes generic drug products for marketing, sale, and/or use throughout the United States, including in this judicial district, at the

direction, under the control, and for the benefit of Apotex Inc. Upon information and belief, Apotex Inc. established Apotex Corp. for the purposes of developing, manufacturing, and distributing its generic drug products throughout the United States, including in this judicial district.

7. Apotex Inc. and Apotex Corp. are collectively referred to hereafter as "Apotex" unless otherwise noted.

8. By a letter dated January 22, 2016, Apotex notified Plaintiff that Apotex had submitted to the FDA ANDA No. 207993 for Fingolimod 0.5 mg capsules, a drug product that is a generic version of GILENYA® ("Apotex's ANDA Product"). The purpose of Apotex's submission of the ANDA was to obtain approval under the Federal Food, Drug, and Cosmetic Act ("FDCA") to engage in the commercial manufacture, use, offer for sale, and/or sale of Apotex's ANDA Product prior to the expiration of U.S. Patent No. 9,187,405 ("the '405 patent").

9. In its Notice Letter, Apotex notified Plaintiff that, as a part of its ANDA, Apotex had filed a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '405 patent asserting that the '405 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of Apotex's ANDA Product.

10. On the basis of this Notice Letter, Novartis filed suit against Apotex for infringement of the '405 patent, which is still pending in this District. *See Novartis Pharms. Corp. v. Apotex Inc. et al.*, C.A. No. 18-cv-1038-LPS (D. Del.). Apotex answered, counterclaimed, and actively participated in this litigation prior to the case being stayed. *See Novartis Pharms. Corp. v. Accord Healthcare Inc., et al*, C.A. No. 18-1043-KAJ, D.I. 237 (D.

Del.). Unlike other defendants, Apotex has not settled with Novartis, converted its Paragraph IV certification to Paragraph III, or otherwise withdrawn its ANDA, and thus appears to continue to pursue final approval from FDA to launch its product prior to expiration of the '405 patent.

11. Upon information and belief, and consistent with their past practices, Apotex Inc. and Apotex Corp. acted collaboratively in the preparation and submission of ANDA No. 207993.

12. Upon information and belief, and consistent with their past practices, following any FDA approval of ANDA No. 207993, Apotex Inc. and Apotex Corp. will work in concert with one another to make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 207993 throughout the United States, and/or import such generic drug products into the United States, including in this judicial district.

13. Apotex committed an act of infringement of the '179 patent in this judicial district by filing ANDA No. 207993 with the intent to make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 207993 in this judicial district, and/or will imminently commit an act of infringement by making, using, offering to sell, and/or selling the same, acts of infringement that will lead to foreseeable harm and injury to Novartis, a Delaware corporation.

14. Apotex Corp. is a Delaware corporation, has extensive contacts with the State of Delaware, and regularly does business in this District. On information and belief, Apotex Corp. is registered with the Delaware Board of Pharmacy, pursuant to Del. Code tit. 24, § 2540, as a licensed "Pharmacy—Wholesale[r]" (License No. A4-0001921) and "Distributor/Manufacturer CSR" (License No. DM-0008873). Moreover, on information and belief, Apotex Corp. has appointed a registered agent in Delaware (located at The Corporation

Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, DE 19801) for the receipt of service of process.

15. Apotex Inc. has extensive contacts with the State of Delaware, including through its subsidiary Apotex Corp., and regularly does business in this District, including through its subsidiary Apotex Corp.

16. Apotex has availed itself of the legal protections of the State of Delaware by, among other things, selecting the State of Delaware as the place of incorporation for Apotex Corp. and admitting jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware. *See, e.g., Pfizer Inc. et al. v. Apotex Inc. et al.*, C.A. No. 19-00747 (D. Del.); *Vanda Pharm. Inc. v. Apotex Inc. et al.*, C.A. No. 19-00685 (D. Del.); *Bayer HealthCare LLC et al. v. Apotex Inc. et al.*, C.A. No. 18-01465 (D. Del.); *Astellas US LLC et al. v. Apotex Inc.*, C.A. No. 18-01675 (D. Del.); *Anacor Pharm., Inc. v. Ascent Pharm., Inc. et al.*, C.A. No. 18-01673 (D. Del.); *Genzyme Corp. et al. v. Apotex Corp. et al.*, C.A. No. 18-01795 (D. Del.); *AstraZeneca AB et al. v. Apotex Inc. et al.*, C.A. No. 18-02010 (D. Del.); *Genentech, Inc. et al. v. Apotex Inc. et al.*, C.A. No. 19-00123 (D. Del.); *Genentech, Inc. et al. v. Apotex Inc. et al.*, C.A. No. 19-00120 (D. Del.); *Merck Sharp & Dohme Corp. v. Apotex Inc. et al.*, C.A. No. 19-00313 (D. Del.); *Pfizer Inc. et al v. Apotex Inc. et al.*, C.A. No. 18-00795 (D. Del.); *Otsuka Pharm. Co. v. Apotex Inc. et al.*, C.A. No. 15-00109 (D. Del.); *Aptalis Pharmatech, Inc. et al. v. Apotex Inc. et al.*, C.A. No. 14-01038 (D. Del.); *Apotex, Inc. et al. v. Senju Pharm. Co., Ltd.*, C.A. No. 12-cv-00196 (D. Del.); *Acorda Therapeutics, Inc. v. Apotex Corp.*, C.A. No. 14-cv-00955 (D. Del.); *Warner Chilcott Co., LLC v. Apotex, Inc.*, C.A. No. 1:14-cv-00998 (D. Del.); *Pfizer Inc. v. Apotex Inc.*, C.A. No. 1:13-cv-02022 (D. Del.); *Boehringer Ingelheim Pharm., Inc. v. Apotex Inc. et al.*, C.A. No. 08-00065 (D. Del.). In

particular, Apotex has admitted jurisdiction, filed counterclaims, and actively litigated two other patent cases related to GILENYA® in this District. *See Novartis AG et al. v. Apotex Inc. et al.*, C.A. No. 15-00975-LPS (D. Del.); *Novartis Pharms. Corp. v. Apotex Inc. et al.*, C.A. No. 18-1038-LPS (D. Del.).

b) Bionpharma Inc.

17. Upon information and belief, Defendant Bionpharma Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 600 Alexander Road, Suite 2-4B, Princeton, NJ 08540.

18. Upon information and belief, Bionpharma Inc. is in the business of, among other things, developing, manufacturing, and selling generic versions of branded pharmaceutical products for the U.S. market, including in this District.

19. Bionpharma Inc. is referred to hereafter as "Bionpharma" unless otherwise noted.

20. By a letter dated June 8, 2017, Bionpharma notified Plaintiff that Bionpharma had submitted to the FDA ANDA No. 210252 for Fingolimod 0.5 mg capsules, a drug product that is a generic version of GILENYA® ("Bionpharma's ANDA Product"). The purpose of Bionpharma's submission of the ANDA was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Bionpharma's ANDA Product prior to the expiration of the '405 patent.

21. In its Notice Letter, Bionpharma notified Plaintiff that, as a part of its ANDA, Bionpharma had filed a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '405

patent asserting that the '405 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of Bionpharma's ANDA Product.

22. On the basis of this Notice Letter, Novartis filed suit against Bionpharma for infringement of the '405 patent, which is still pending in this District. *See Novartis Pharms. Corp. v. Accord Healthcare Inc., et al*, C.A. No. 18-1043-KAJ (D. Del.). Bionpharma answered, counterclaimed, and actively participated in this litigation prior to the case being stayed. *Id.*, D.I. 353. Unlike other defendants, Bionpharma has not settled with Novartis, converted its Paragraph IV certification to Paragraph III, or otherwise withdrawn its ANDA, and thus appears to continue to pursue final approval from FDA to launch its product prior to expiration of the '405 patent.

23. Upon information and belief, and consistent with its past practices, following any FDA approval of ANDA No. 210252, Bionpharma will make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 210252 throughout the United States, and/or import such generic drug products into the United States, including in this judicial district.

24. Bionpharma has committed an act of infringement of the '179 patent in this judicial district by filing ANDA No. 210252 with the intent to make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 210252 in this judicial district, and/or will imminently commit an act of infringement by making, using, offering to sell, and/or selling the same, acts of infringement that will lead to foreseeable harm and injury to Novartis, a Delaware corporation.

25. Bionpharma has extensive contacts with the State of Delaware, regularly conducts business in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos, has purposefully availed itself of the privilege of

doing business in the State of Delaware, and intends to sell in the State of Delaware the product described in ANDA No. 210252 upon approval. Furthermore, upon information and belief, Bionpharma has a regular and established place of business in this judicial district.

26. Bionpharma has availed itself of the legal protections of the State of Delaware by, among other things, admitting jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware. *See, e.g.*, *Patheon Softgels Inc. et al. v. Apotex Inc. et al.*, 18-00003 (D. Del.); *Bristol-Myers Squibb Co. et al. v. Bionpharma Inc.*, 17-00400 (D. Del.); *Silvergate Pharm. Inc. v. Bionpharma Inc.*, 16-00876 (D. Del.). In particular, Bionpharma has admitted jurisdiction, filed counterclaims, and actively litigated another patent case related to GILENYA® in this District. *See Novartis Pharms. Corp. v. Accord Healthcare Inc., et al.*, C.A. No. 18-1043-KAJ (D. Del.).

c) Emcure Pharmaceuticals; Heritage Pharmaceuticals Inc.

27. Upon information and belief, Defendant Emcure Pharmaceuticals is a corporation organized and existing under the laws of India, having a principal place of business at Emcure House, T184, M.I.D.C., Bhosari, Pune, 411026, Maharashtra, India.

28. Upon information and belief, Defendant Heritage Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 12 Christopher Way, Suite 300, Eatontown, New Jersey 07724.

29. Upon information and belief, Emcure Pharmaceuticals is in the business of, among other things, developing, manufacturing, and selling generic versions of branded pharmaceutical products for the U.S. market. Upon information and belief, Heritage Pharmaceuticals Inc. is a wholly-owned subsidiary of Emcure Pharmaceuticals and is controlled and/or dominated by Emcure Pharmaceuticals. Upon information and belief, Heritage

Pharmaceuticals Inc. develops, manufactures, and/or distributes generic drug products for marketing, sale, and/or use throughout the United States, including in this judicial district, at the direction, under the control, and for the benefit of Emcure Pharmaceuticals.

30. Emcure Pharmaceuticals and Heritage Pharmaceuticals Inc. are collectively referred to hereafter as "Emcure" unless otherwise noted.

31. By a letter dated March 1, 2016, Emcure notified Plaintiff that Emcure had submitted to the FDA ANDA No. 207927 for Fingolimod 0.5 mg capsules, a drug product that is a generic version of GILENYA® ("Emcure's ANDA Product"). The purpose of Emcure's submission of the ANDA was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Emcure's ANDA Product prior to the expiration of the '405 patent.

32. In its Notice Letter, Emcure notified Plaintiff that, as a part of its ANDA, Emcure had filed a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '405 patent asserting that the '405 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of Emcure's ANDA Product.

33. On the basis of this Notice Letter, Novartis filed suit against Emcure for infringement of the '405 patent, which is still pending in this District. *See Novartis Pharms. Corp. v. Accord Healthcare Inc., et al*, C.A. No. 18-1043-KAJ (D. Del.). Emcure answered and actively participated in this litigation prior to the case being stayed. *Id.*, D.I. 302. Unlike other defendants, Emcure has not settled with Novartis, converted its Paragraph IV certification to Paragraph III, or otherwise withdrawn its ANDA, and thus appears to continue to pursue final approval from FDA to launch its product prior to expiration of the '405 patent.

34. Upon information and belief, and consistent with their past practices, Emcure Pharmaceuticals and Heritage Pharmaceuticals Inc. acted collaboratively in the preparation and submission of ANDA No. 207927.

35. Upon information and belief, and consistent with their past practices, following any FDA approval of ANDA No. 207927, Emcure Pharmaceuticals and Heritage Pharmaceuticals Inc., Inc. will work in concert with one another to make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 207927 throughout the United States, and/or import such generic drug products into the United States, including in this judicial district.

36. Emcure has committed an act of infringement of the '179 patent in this judicial district by filing ANDA No. 207927 with the intent to make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 207927 in this judicial district, and/or will imminently commit an act of infringement by making, using, offering to sell, and/or selling the same, acts of infringement that will lead to foreseeable harm and injury to Novartis, a Delaware corporation.

37. Emcure has extensive contacts with the State of Delaware, regularly conducts business in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos, has purposefully availed itself of the privilege of doing business in the State of Delaware, and intends to sell in the State of Delaware the product described in ANDA No. 207927 upon approval. Furthermore, upon information and belief, Emcure has a regular and established place of business in this judicial district.

38. Emcure has availed itself of the legal protections of the State of Delaware by, among other things, admitting jurisdiction and asserting counterclaims in lawsuits filed in the

United States District Court for the District of Delaware. *See, e.g.*, *Bristol-Myers Squibb Co. et al. v. Emcure Pharm. Ltd.*, 17-00402 (D. Del.); *Cephalon, Inc. v. Emcure Pharm., Ltd. et al.*, C.A. No. 14-0335 (D. Del.). In particular, Emcure has admitted jurisdiction and actively litigated another patent case related to GILENYA® in this District. *See Novartis Pharms. Corp. v. Accord Healthcare Inc., et al.*, C.A. No. 18-1043-KAJ (D. Del.).

d) Ezra Ventures, LLC

39. Upon information and belief, Defendant Ezra Ventures, LLC is a corporation organized and existing under the laws of the State of Arkansas, having a principal place of business at 401 S. Cedar Street, Little Rock, Arkansas, 72205.

40. Upon information and belief, Ezra Ventures, LLC is in the business of, among other things, developing, manufacturing, and selling generic versions of branded pharmaceutical products for the U.S. market, including in this District.

41. Ezra Ventures, LLC is referred to hereafter as "Ezra" unless otherwise noted.

42. By a letter dated February 2, 2017, Ezra notified Plaintiff that Ezra had submitted to the FDA ANDA No. 207945 for Fingolimod 0.5 mg capsules, a drug product that is a generic version of GILENYA® ("Ezra's ANDA Product"). The purpose of Ezra's submission of the ANDA was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Ezra's ANDA Product prior to the expiration of the '405 patent.

43. In its Notice Letter, Ezra notified Plaintiff that, as a part of its ANDA, Ezra had filed a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '405 patent asserting that the '405 patent is

invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of Ezra's ANDA Product.

44. On the basis of this Notice Letter, Novartis filed suit against Ezra for infringement of the '405 patent, which is still pending in this District. *See Novartis Pharms. Corp. v. Accord Healthcare Inc., et al.*, C.A. No. 18-1043-KAJ (D. Del.). Ezra answered, counterclaimed, and actively participated in this litigation prior to the case being stayed. *Id.*, D.I. 351. Unlike other defendants, Ezra has not settled with Novartis, converted its Paragraph IV certification to Paragraph III, or otherwise withdrawn its ANDA, and thus appears to continue to pursue final approval from FDA to launch its product prior to expiration of the '405 patent.

45. Upon information and belief, and consistent with its past practices, following any FDA approval of ANDA No. 207945, Ezra will make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 207945 throughout the United States, and/or import such generic drug products into the United States, including in this judicial district.

46. Ezra has committed an act of infringement of the '179 patent in this judicial district by filing ANDA No. 207945 with the intent to make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 207945 in this judicial district, and/or will imminently commit an act of infringement by making, using, offering to sell, and/or selling the same, acts of infringement that will lead to foreseeable harm and injury to Novartis, a Delaware corporation.

47. Ezra has availed itself of the legal protections of the State of Delaware by, among other things, filing counterclaims and actively litigated two other patent cases related to GILENYA® in this District. *See, e.g., Novartis AG et al. v. Ezra Ventures, LLC*, C.A. No. 15-

00150-LPS (D. Del.); *Novartis Pharms. Corp. v. Accord Healthcare Inc., et al.*, C.A. No. 18-1043-KAJ (D. Del.). Ezra admitted jurisdiction in the most recent GILENYA® case. *Novartis Pharms. Corp. v. Accord Healthcare Inc., et al.*, C.A. No. 18-1043-KAJ (D. Del.). Ezra has extensive contacts with the State of Delaware, regularly conducts business in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos, has purposefully availed itself of the privilege of doing business in the State of Delaware, and intends to sell in the State of Delaware the product described in ANDA No. 207945 upon approval.

e) Glenmark Pharmaceuticals Inc., USA; Glenmark Pharmaceuticals Limited

48. Upon information and belief, Defendant Glenmark Pharmaceuticals Limited is a corporation organized and existing under the laws of India, having a principal place of business at Glenmark House, HDO-Corporate Building, Wing -A, B D Sawant Marg, Chakala, Off Western Express Highway, Mumbai 400099, Maharashtra, India.

49. Upon information and belief, Defendant Glenmark Pharmaceuticals Inc., USA is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 750 Corporate Drive, Mahwah, New Jersey 07430.

50. Upon information and belief, Glenmark Pharmaceuticals Limited is in the business of, among other things, developing, manufacturing, and selling generic versions of branded pharmaceutical products for the U.S. market. Upon information and belief, Glenmark Pharmaceuticals Inc., USA is a wholly-owned subsidiary of Glenmark Pharmaceuticals Limited and is controlled and/or dominated by Glenmark Pharmaceuticals Limited. Upon information and belief, Glenmark Pharmaceuticals Inc., USA develops, manufactures and/or distributes

generic drug products for marketing, sale, and/or use throughout the United States, including in this judicial district, at the direction, under the control, and for the benefit of Glenmark Pharmaceuticals Limited.

51. Glenmark Pharmaceuticals Limited and Glenmark Pharmaceuticals Inc., USA are collectively referred to hereafter as "Glenmark" unless otherwise noted.

52. By a letter dated October 6, 2016, Glenmark notified Plaintiff that Glenmark had submitted to the FDA ANDA No. 207985 for Fingolimod 0.5 mg capsules, a drug product that is a generic version of GILENYA® ("Glenmark's ANDA Product"). The purpose of Glenmark's submission of the ANDA was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Glenmark's ANDA Product prior to the expiration of the '405 patent.

53. In its Notice Letter, Glenmark notified Plaintiff that, as a part of its ANDA, Glenmark had filed a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '405 patent asserting that the '405 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of Glenmark's ANDA Product.

54. On the basis of this Notice Letter, Novartis filed suit against Glenmark for infringement of the '405 patent, which is still pending in this District. *See Novartis Pharms. Corp. v. Accord Healthcare Inc., et al.*, C.A. No. 18-1043-KAJ (D. Del.). Glenmark answered, counterclaimed, and actively participated in this litigation prior to the case being stayed. *Id.*, D.I. 344. Unlike other defendants, Glenmark has not settled with Novartis, converted its Paragraph IV certification to Paragraph III, or otherwise withdrawn its ANDA, and thus appears to continue to pursue final approval from FDA to launch its product prior to expiration of the '405 patent.

55. Upon information and belief, and consistent with their past practices, Glenmark Pharmaceuticals Limited and Glenmark Pharmaceuticals Inc., USA acted collaboratively in the preparation and submission of ANDA No. 207985.

56. Upon information and belief, and consistent with their past practices, following any FDA approval of ANDA No. 207985, Glenmark Pharmaceuticals Limited and Glenmark Pharmaceuticals Inc., USA, Inc. will work in concert with one another to make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 207985 throughout the United States, and/or import such generic drug products into the United States, including in this judicial district.

57. Glenmark has committed an act of infringement of the '179 patent in this judicial district by filing ANDA No. 207985 with the intent to make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 207985 in this judicial district, and/or will imminently commit an act of infringement by making, using, offering to sell, and/or selling the same, acts of infringement that will lead to foreseeable harm and injury to Novartis, a Delaware corporation.

58. Glenmark has extensive contacts with the State of Delaware, regularly conducts business in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos, has purposefully availed itself of the privilege of doing business in the State of Delaware, and intends to sell in the State of Delaware the product described in ANDA No. 207985 upon approval. Furthermore, upon information and belief, Glenmark has a regular and established place of business in this judicial district.

59. Glenmark has availed itself of the legal protections of the State of Delaware by, among other things, admitting jurisdiction and asserting counterclaims in lawsuits

filed in the United States District Court for the District of Delaware. *See, e.g.*, *Pfizer Inc. et al. v. Glenmark Pharm. Ltd. et al.* C.A. No. 19-01209 (D. Del.); *Glenmark Pharm. Ltd et al. v. GlaxoSmithKline PLC et al.*, C.A. No. 13-00135 (D. Del.); *Delcor Asset Corp. v. Glenmark Pharm. et al.*, C.A. No. 18-00460 (D. Del.). In particular, Glenmark has admitted jurisdiction, filed counterclaims, and actively litigated another patent case related to GILENYA® in this District. *See Novartis Pharms. Corp. v. Accord Healthcare Inc., et al.*, C.A. No. 18-1043-KAJ (D. Del.).

f) HEC Pharm Co., Ltd.; HEC Pharm USA Inc.

60. Upon information and belief, Defendant HEC Pharm Co., Ltd. is a corporation organized and existing under the laws of China, having a principal place of business at Binjiang Road 62, Yidu, Yichang, 443300, Hubei, China.

61. Upon information and belief, Defendant HEC Pharm USA Inc. is a corporation organized and existing under the laws of the State of New Jersey, having a principal place of business at 116 Village Blvd, Suite 200, Princeton, NJ 08540.

62. Upon information and belief, HEC Pharm Co., Ltd. is in the business of, among other things, developing, manufacturing, and selling generic versions of branded pharmaceutical products for the U.S. market. Upon information and belief, HEC Pharm USA Inc. develops, manufactures, and/or distributes generic drug products for marketing, sale, and/or use throughout the United States, including in this judicial district, at the direction, under the control, and for the benefit of HEC Pharm Co., Ltd.

63. HEC Pharm Co., Ltd. and HEC Pharm USA Inc. are collectively referred to hereafter as "HEC" unless otherwise noted.

64. By a letter dated January 28, 2016, HEC notified Plaintiff that HEC had submitted to the FDA ANDA No. 207939 for Fingolimod 0.5 mg capsules, a drug product that is a generic version of GILENYA® ("HEC's ANDA Product"). The purpose of HEC's submission of the ANDA was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of HEC's ANDA Product prior to the expiration of the '405 patent.

65. In its Notice Letter, HEC notified Plaintiff that, as a part of its ANDA, HEC had filed a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '405 patent asserting that the '405 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of HEC's ANDA Product.

66. On the basis of this Notice Letter, Novartis filed suit against HEC for infringement of the '405 patent, which is still pending in this District. *See Novartis Pharms. Corp. v. Accord Healthcare Inc., et al.*, C.A. No. 18-1043-KAJ (D. Del.). HEC answered, counterclaimed, and is actively participating in this litigation. Unlike other defendants, HEC has not settled with Novartis or converted its Paragraph IV certification to Paragraph III, and HEC's ANDA recently received final approval from FDA. *See* https://www.fda.gov/news-events/press-announcements/fda-approves-first-generics-gilenya. HEC thus appears to continue to pursue generic launch prior to expiration of the '405 patent.

67. Upon information and belief, and consistent with their past practices HEC Pharm Co., Ltd. and HEC Pharm USA Inc. acted collaboratively in the preparation and submission of ANDA No. 207939.

68. Upon information and belief, and consistent with their past practices, following any FDA approval of ANDA No. 207939, HEC Pharm Co., Ltd. and HEC Pharm USA

Inc. will work in concert with one another to make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 207939 throughout the United States, and/or import such generic drug products into the United States, including in this judicial district.

69. HEC has committed an act of infringement of the '179 patent in this judicial district by filing ANDA No. 207939 with the intent to make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 207939 in this judicial district, and/or will imminently commit an act of infringement by making, using, offering to sell, and/or selling the same, acts of infringement that will lead to foreseeable harm and injury to Novartis, a Delaware corporation.

70. HEC has extensive contacts with the State of Delaware, regularly conducts business in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos, has purposefully availed itself of the privilege of doing business in the State of Delaware, and intends to sell in the State of Delaware the product described in ANDA No. 207939 upon approval. Furthermore, upon information and belief, HEC has a regular and established place of business in this judicial district.

71. HEC has availed itself of the legal protections of the State of Delaware by, among other things, admitting jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware. *See, e.g., Bristol-Myers Squibb Co. et al. v. Sunshine Lake Pharma Co., Ltd. et al.*, C.A. No. 17-00380 (D. Del.); *Astrazeneca LP et al. v. HEC Pharm Co., Ltd. et al.*, C.A. No. 15-1041 (D. Del.). In particular, HEC has filed counterclaims and actively litigated two other patent cases related to GILENYA® in this District. *See Novartis AG et al v. HEC Pharm Co., Ltd. et al.*, C.A. No. 15-00151-LPS (D. Del.); *Novartis Pharms. Corp. v. Accord Healthcare Inc., et al.*, C.A. No. 18-1043-KAJ (D. Del.).

HEC admitted jurisdiction in the most recent GILENYA® case. *Novartis Pharms. Corp. v. Accord Healthcare Inc., et al.*, C.A. No. 18-1043-KAJ (D. Del.).

g) Hetero USA Inc.; Hetero Labs Limited Unit-V; Hetero Labs Limited

72. Upon information and belief, Defendant Hetero Labs Limited is a corporation organized and existing under the laws of India, having a principal place of business at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad 500 018, Andhra Pradesh, India.

73. Upon information and belief, Defendant Hetero Labs Limited Unit-V is a corporation organized and existing under the laws of India, having a principal place of business at Polepally, Jadcherla, Mahabubnagar, 509301, Andhra Pradesh, India.

74. Upon information and belief, Defendant Hetero USA Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1035 Centennial Avenue, Piscataway, New Jersey 08854.

75. Upon information and belief, Hetero Labs Limited is in the business of, among other things, developing, manufacturing, and selling generic versions of branded pharmaceutical products for the U.S. market. Upon information and belief, Hetero USA Inc. and Hetero Labs Limited Unit-V are wholly-owned subsidiaries of Hetero Labs Limited and are controlled and/or dominated by Hetero Labs Limited. Upon information and belief, Hetero USA Inc. develops, manufactures, and/or distributes generic drug products for marketing, sale, and/or use throughout the United States, including in this judicial district, at the direction, under the control, and for the benefit of Hetero Labs Limited and Hetero Labs Limited Unit-V.

76. Hetero Labs Limited, Hetero Labs Limited Unit-V, and Hetero USA Inc. are collectively referred to hereafter as “Hetero” unless otherwise noted.

77. By a letter dated June 13, 2016, Hetero notified Plaintiff that Hetero had submitted to the FDA ANDA No. 207933 for Fingolimod 0.5 mg capsules, a drug product that is a generic version of GILENYA® ("Hetero's ANDA Product"). The purpose of Hetero's submission of the ANDA was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Hetero's ANDA Product prior to the expiration of the '405 patent.

78. In its Notice Letter, Hetero notified Plaintiff that, as a part of its ANDA, Hetero had filed a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '405 patent asserting that the '405 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of Hetero's ANDA Product.

79. On the basis of this Notice Letter, Novartis filed suit against Hetero for infringement of the '405 patent, which is still pending in this District. *See Novartis Pharms. Corp. v. Accord Healthcare Inc., et al.*, C.A. No. 18-1043-KAJ (D. Del.). Hetero answered, counterclaimed, and is actively participating in this litigation. Unlike other defendants, Hetero has not settled with Novartis, converted its Paragraph IV certification to Paragraph III, or otherwise withdrawn its ANDA, and thus appears to continue to pursue final approval from FDA to launch its product prior to expiration of the '405 patent.

80. Upon information and belief, and consistent with their past practices, Hetero Labs Limited, Hetero Labs Limited Unit-V, and Hetero USA Inc. acted collaboratively in the preparation and submission of ANDA No. 207933.

81. Upon information and belief, and consistent with their past practices, following any FDA approval of ANDA No. 207933, Hetero Labs Limited, Hetero Labs Limited

Unit-V, and Hetero USA Inc., Inc. will work in concert with one another to make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 207933 throughout the United States, and/or import such generic drug products into the United States, including in this judicial district.

82. Hetero has committed an act of infringement of the '179 patent in this judicial district by filing ANDA No. 207933 with the intent to make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 207933 in this judicial district, and/or will imminently commit an act of infringement by making, using, offering to sell, and/or selling the same, acts of infringement that will lead to foreseeable harm and injury to Novartis, a Delaware corporation.

83. Hetero has extensive contacts with the State of Delaware, regularly conducts business in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos, has purposefully availed itself of the privilege of doing business in the State of Delaware, and intends to sell in the State of Delaware the product described in ANDA No. 207933 upon approval. Furthermore, upon information and belief, Hetero has a regular and established place of business in this judicial district.

84. Hetero has availed itself of the legal protections of the State of Delaware by, among other things, admitting jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware. *See, e.g., Allergan USA, Inc. et al. v. Aurobindo Pharma Ltd. et al.*, C.A. No.19-01727 (D. Del.); *Pfizer Inc. et al. v. Hetero USA Inc.et al.*, C.A. No. 19-00751 (D. Del.); *Genentech, Inc. et al. v. Hetero Labs Ltd. et al.*, C.A. No. 19-00178 (D. Del.); *Vifor Fresenius Med. Care Renal Pharma Ltd. et al. v. Annora Pharma Private Ltd. et al.*, C.A. No. 18-cv-01996 (D. Del.); *Boehringer Ingelheim Pharm. Inc. et al. v.*

Annora Pharma Private Ltd. et al., C.A. No. 18-01786 (D. Del.); *Boehringer Ingelheim Pharm. Inc. et al. v. Mankind Pharma Ltd. et al.*, C.A. No. 18-01689 (D. Del.); *Millennium Pharm., Inc. v. Hetero Labs Ltd. et al.*, C.A. No. 18-01639 (D. Del.); *Biogen Int'l GmbH et al v. Hetero USA Inc. et al.*, C.A. No. 17-00825 (D. Del.); *Bristol-Myers Squibb Co. et al. v. Hetero USA Inc. et al.*, C.A. No. 17-00376 (D. Del.), *Amgen Inc. v. Hetero USA Inc. et al.*, C.A. No. 16-00928 (D. Del.); *UCB, Inc. et al. v. Hetero USA Inc. et al.*, C.A. No. 16-00452 (D. Del.); *Cephalon, Inc. v. Dr. Reddy's Labs., Ltd. et al.*, C.A. No. 15-00179 (D. Del.); *AbbVie Inc. et al v. Hetero USA Inc. et al.*, C.A. No. 14-00543 (D. Del.); *Otsuka Pharm. Co. Ltd. v. Hetero USA Inc. et al.*, C.A. No. 14-00421 (D. Del.); *Teijin Ltd. et al. v. Hetero USA Inc. et al.*, C.A. No. 14-00166 (D. Del.). In particular, Hetero has admitted jurisdiction, filed counterclaims, and actively litigated another patent case related to GILENYA® in this District. *See Novartis Pharms. Corp. v. Accord Healthcare Inc., et al.*, C.A. No. 18-1043-KAJ (D. Del.).

h) Prinston Pharmaceutical Inc.

85. Upon information and belief, Defendant Prinston Pharmaceutical Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 2002 Eastpark Blvd., Cranbury, NJ 08512.

86. Upon information and belief, Prinston Pharmaceutical Inc. is in the business of, among other things, developing, manufacturing, and selling generic versions of branded pharmaceutical products for the U.S. market, including in this District.

87. Prinston Pharmaceutical Inc. is referred to hereafter as "Prinston" unless otherwise noted.

88. By a letter dated April 28, 2017, Prinston notified Plaintiff that Prinston had submitted to the FDA ANDA No. 208003 for Fingolimod 0.5 mg capsules, a drug product

that is a generic version of GILENYA® ("Prinston's ANDA Product"). The purpose of Prinston's submission of the ANDA was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Prinston's ANDA Product prior to the expiration of the '405 patent.

89. In its Notice Letter, Prinston notified Plaintiff that, as a part of its ANDA, Prinston had filed a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '405 patent asserting that the '405 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of Prinston's ANDA Product.

90. On the basis of this Notice Letter, Novartis filed suit against Prinston for infringement of the '405 patent, which is still pending in this District. *See Novartis Pharms. Corp. v. Accord Healthcare Inc., et al*, C.A. No. 18-1043-KAJ (D. Del.). Prinston answered, counterclaimed, and actively participated in this litigation prior to the case being stayed. *Id.*, D.I. 511. Unlike other defendants, Prinston has not settled with Novartis, converted its Paragraph IV certification to Paragraph III, or otherwise withdrawn its ANDA, and thus appears to continue to pursue final approval from FDA to launch its product prior to expiration of the '405 patent.

91. Upon information and belief, and consistent with its past practices, following any FDA approval of ANDA No. 208003, Prinston will make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 208003 throughout the United States, and/or import such generic drug products into the United States, including in this judicial district.

92. Prinston has committed an act of infringement of the '179 patent in this judicial district by filing ANDA No. 208003 with the intent to make, use, offer to sell, and/or sell

the generic drug products that are the subject of ANDA No. 208003 in this judicial district, and/or will imminently commit an act of infringement by making, using, offering to sell, and/or selling the same, acts of infringement that will lead to foreseeable harm and injury to Novartis, a Delaware corporation.

93. Prinston has extensive contacts with the State of Delaware, regularly conducts business in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos, has purposefully availed itself of the privilege of doing business in the State of Delaware, and intends to sell in the State of Delaware the product described in ANDA No. 208003 upon approval. Furthermore, upon information and belief, Prinston has a regular and established place of business in this judicial district.

94. Prinston has availed itself of the legal protections of the State of Delaware by, among other things, admitting jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware. *See, e.g.*, *Boehringer Ingelheim Pharm. Inc. et al. v. Prinston Pharm. Inc. et al.*, C.A. No. 19-01499 (D. Del.); *Boehringer Ingelheim Pharm. Inc. et al. v. Prinston Pharm. Inc.*, C.A. No. 8-01787 (D. Del.); *Astellas Pharma Inc. et al. v. Prinston Pharm. Inc.*, C.A. No. 16-00943 (D. Del.); *AstraZeneca LP et al. v. Prinston Pharm. Inc.*, No. C.A. No. 15-01057 (D. Del.); *Bayer Intellectual Prop. GMBH et al. v. Aurobindo Pharma Ltd. et al.*, C.A. No. 15-00902 (D. Del.); *Teijin Ltd. et al. v. Prinston Pharm. Inc.*, C.A. No. 14-00854 (D. Del.). In particular, Prinston has admitted jurisdiction, filed counterclaims, and actively litigated another patent case related to GILENYA® in this District. *See Novartis Pharms. Corp. v. Accord Healthcare Inc., et al.*, C.A. No. 18-1043-KAJ (D. Del.).

i) Strides Global Pharma Private Limited; Strides Pharma, Inc.

95. Upon information and belief, Defendant Strides Global Pharma Private Limited is a corporation organized and existing under the laws of Singapore, having a principal place of business at No. 8 Eu Tong Sen Street, #15-93, The Central, Singapore—059818.

96. Upon information and belief, Defendant Strides Pharma, Inc. is a corporation organized and existing under the laws of the State of New Jersey, having a principal place of business at 2 Tower Center Blvd., Suite 1102, East Brunswick, NJ 08816.

97. Upon information and belief, Strides Global Pharma Private Limited is in the business of, among other things, developing, manufacturing, and selling generic versions of branded pharmaceutical products for the U.S. market. Upon information and belief, Strides Pharma, Inc. is a wholly-owned subsidiary of Strides Global Pharma Private Limited and is controlled and/or dominated by Strides Global Pharma Private Limited. Upon information and belief, Strides Pharma, Inc. develops, manufactures, and/or distributes generic drug products for marketing, sale, and/or use throughout the United States, including in this judicial district, at the direction, under the control, and for the benefit of Strides Global Pharma Private Limited.

98. Strides Global Pharma Private Limited and Strides Pharma, Inc. are collectively referred to hereafter as "Strides" unless otherwise noted.

99. By a letter dated January 22, 2016, Strides notified Plaintiff that Strides had submitted to the FDA ANDA No. 207971 for Fingolimod 0.5 mg capsules, a drug product that is a generic version of GILENYA® ("Strides's ANDA Product"). The purpose of Strides's submission of the ANDA was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Strides's ANDA Product prior to the expiration of the '405 patent.

100. In its Notice Letter, Strides notified Plaintiff that, as a part of its ANDA, Strides had filed a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '405 patent asserting that the '405 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of Strides's ANDA Product.

101. On the basis of this Notice Letter, Novartis filed suit against Strides for infringement of the '405 patent, which is still currently stayed in this District. *See Novartis Pharms. Corp. v. Accord Healthcare Inc., et al*, C.A. No. 18-1043-KAJ, D.I. 108 (D. Del.).

102. Upon information and belief, and consistent with their past practices, Strides Global Pharma Private Limited and Strides Pharma, Inc. acted collaboratively in the preparation and submission of ANDA No. 207971.

103. Upon information and belief, and consistent with their past practices, following any FDA approval of ANDA No. 207971, Strides Global Pharma Private Limited and Strides Pharma, Inc. will work in concert with one another to make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 207971 throughout the United States, and/or import such generic drug products into the United States, including in this judicial district.

104. Strides has committed an act of infringement of the '179 patent in this judicial district by filing ANDA No. 207971 with the intent to make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 207971 in this judicial district, and/or will imminently commit an act of infringement by making, using, offering to sell, and/or selling the same, acts of infringement that will lead to foreseeable harm and injury to Novartis, a Delaware corporation.

105. Strides has extensive contacts with the State of Delaware, regularly conducts business in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos, has purposefully availed itself of the privilege of doing business in the State of Delaware, and intends to sell in the State of Delaware the product described in ANDA No. 207971 upon approval. Furthermore, upon information and belief, Strides has a regular and established place of business in this judicial district.

106. Strides has availed itself of the legal protections of the State of Delaware by, among other things, admitting jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware. *See, e.g.*, *Forest Labs. Holdings, Ltd. et al. v. Strides Pharma Glob. PTE Ltd. et al.*, C.A. No. 17-01394 (D. Del.); *Amgen Inc., v. Strides Pharma Glob. PTE Ltd. et al.*, C.A. No. 16-00881 (D. Del.); *Takeda Pharms. U.S.A., Inc. v. Strides Pharma Glob. PTE Ltd. et al.*, C.A. No. 17-01690 (D. Del.). In particular, Strides is currently a stayed party to another patent case related to GILENYA® in this District. *See Novartis Pharms. Corp. v. Accord Healthcare Inc., et al.*, C.A. No. 18-1043-KAJ (D. Del.).

j) Zydus Pharmaceuticals (USA) Inc.; Cadila Healthcare Limited

107. Upon information and belief, Defendant Cadila Healthcare Limited is a corporation organized and existing under the laws of India, having a principal place of business at Zydus Tower, Satellite Cross Roads, Ahmedabad-380015, Gujarat, India.

108. Upon information and belief, Defendant Zydus Pharmaceuticals (USA) Inc. is a corporation organized and existing under the laws of the State of New Jersey, having a principal place of business at 73 Route 31 North, Pennington, NJ 08534.

109. Upon information and belief, Cadila Healthcare Limited is in the business of, among other things, developing, manufacturing, and selling generic versions of branded

pharmaceutical products for the U.S. market. Upon information and belief, Zydus Pharmaceuticals (USA) Inc. is a wholly-owned subsidiary of Cadila Healthcare Limited and is controlled and/or dominated by Cadila Healthcare Limited. Upon information and belief, Zydus Pharmaceuticals (USA) Inc. develops, manufactures, and/or distributes generic drug products for marketing, sale, and/or use throughout the United States, including in this judicial district, at the direction, under the control, and for the benefit of Cadila Healthcare Limited.

110. Cadila Healthcare Limited and Zydus Pharmaceuticals (USA) Inc. are collectively referred to hereafter as "Zydus" unless otherwise noted.

111. By a letter dated August 19, 2016, Zydus notified Plaintiff that Zydus had submitted to the FDA ANDA No. 207994 for Fingolimod 0.5 mg capsules, a drug product that is a generic version of GILENYA® ("Zydus's ANDA Product"). The purpose of Zydus's submission of the ANDA was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Zydus's ANDA Product prior to the expiration of the '405 patent.

112. In its Notice Letter, Zydus notified Plaintiff that, as a part of its ANDA, Zydus had filed a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '405 patent asserting that the '405 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of Zydus's ANDA Product.

113. On the basis of this Notice Letter, Novartis filed suit against Zydus for infringement of the '405 patent, which is still pending in this District. *See Novartis Pharms. Corp. v. Accord Healthcare Inc., et al.*, C.A. No. 18-1043-KAJ (D. Del.). Zydus answered and is actively participating in this litigation. Unlike other defendants, Zydus has not settled with

Novartis, converted its Paragraph IV certification to Paragraph III, or otherwise withdrawn its ANDA, and thus appears to continue to pursue final approval from FDA to launch its product prior to expiration of the ’405 patent.

114. Upon information and belief, and consistent with their past practices, Cadila Healthcare Limited and Zydus Pharmaceuticals (USA) Inc. acted collaboratively in the preparation and submission of ANDA No. 207994.

115. Upon information and belief, and consistent with their past practices, following any FDA approval of ANDA No. 207994, Cadila Healthcare Limited and Zydus Pharmaceuticals (USA) Inc. will work in concert with one another to make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 207994 throughout the United States, and/or import such generic drug products into the United States, including in this judicial district.

116. Zydus has committed an act of infringement of the ’179 patent in this judicial district by filing ANDA No. 207994 with the intent to make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 207994 in this judicial district, and/or will imminently commit an act of infringement by making, using, offering to sell, and/or selling the same, acts of infringement that will lead to foreseeable harm and injury to Novartis, a Delaware corporation.

117. Zydus has extensive contacts with the State of Delaware, regularly conducts business in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos, has purposefully availed itself of the privilege of doing business in the State of Delaware, and intends to sell in the State of Delaware the product

described in ANDA No. 207994 upon approval. Furthermore, upon information and belief, Zydus has a regular and established place of business in this judicial district.

118. Zydus has availed itself of the legal protections of the State of Delaware by, among other things, admitting jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware. *See, e.g.*, *Allergan USA, Inc. et al. v. Aurobindo Pharma Ltd. et al.*, C.A. No. 19-01727 (D. Del.); *Boehringer Ingelheim Pharm. Inc. et al. v. Zydus Pharm. (USA) Inc. et al.*, C.A. No. 19-01501 (D. Del.); *Boehringer Ingelheim Pharm. Inc. et al. v. Zydus Pharm. (USA) Inc. et al.*, C.A. No. 19-01295 (D. Del.); *Pfizer Inc. et al. v. Zydus Pharm. (USA) Inc. et al.*, C.A. No. 19-00760 (D. Del.); *Biogen Int'l GmbH v. Zydus Pharm. (USA) Inc.*, C.A. No. 19-cv-00333 (D. Del.); *Merck Sharp & Dohme Corp. v. Zydus Pharm. (USA) Inc. et al.*, C.A. No. 19-00314 (D. Del.); *Pharmacyclics LLC et al. v. Zydus Worldwide DMCC et al.*, C.A. No. 19-00143 (D. Del.); *Boehringer Ingelheim Pharm. Inc. et al. v. Zydus Pharm. (USA) Inc. et al.*, C.A. No. 18-01763 (D. Del.); *Anacor Pharm., Inc. v. Ascent Pharm., Inc. et al.*, C.A. No. 18-01673 (D. Del.); *Millennium Pharm., Inc. v. Zydus Pharm. (USA) Inc. et al.*, C.A. No. 17-00423 (D. Del.); *Sanofi-Aventis U.S. LLC et al. v. Zydus Pharm. (USA) Inc. et al.*, C.A. No. 17-00034 (D. Del.); *Astellas Pharma, Inc. et al. v. Zydus Pharm. (USA) Inc. et al.*, C.A. No. 16-01167 (D. Del.); *Amgen Inc. v. Zydus Pharm. (USA) Inc. et al.*, C.A. No. 16- 00853 (D. Del.); *Genzyme Corp. et al. v. Zydus Pharm. (USA) Inc.*, C.A. No. 16-00540 (D. Del.); *Upsher-Smith Labs, Inc. v. Zydus Pharm. (USA) Inc. et al.*, C.A. No. 16-00248 (D. Del.). In particular, Zydus has admitted jurisdiction and actively litigated another patent case related to GILENYA® in this District. *See Novartis Pharms. Corp. v. Accord Healthcare Inc., et al.*, C.A. No. 18-1043-KAJ (D. Del.).

JURISDICTION AND VENUE

119. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100, *et seq.*, and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a). Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

120. This Court has personal jurisdiction over each Defendant because, among other things, each has committed, or aided, abetted, contributed to, or participated in the commission of, tortious acts of patent infringement in filing each ANDA that has led to foreseeable harm and injury to Novartis, a Delaware corporation, and will imminently commit, or aid, abet, contribute to, or participate in the commission of, a tortious act of patent infringement by selling its ANDA Product which will lead to foreseeable harm and injury to Novartis, a Delaware corporation.

121. This Court also has personal jurisdiction over each Defendant because each of its affiliations with the State of Delaware, including in many instances by virtue of its incorporation in Delaware or the incorporation in Delaware of subsidiaries, are so continuous and systematic as to render each Defendant essentially at home in this forum.

122. This Court also has personal jurisdiction over each Defendant because each has frequently availed itself of the legal protections of the State of Delaware by, among other things, selecting the State of Delaware as the place of incorporation for itself and their subsidiaries and admitting jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware.

123. For these reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over each Defendant.

124. Venue is proper in this Court under both 28 U.S.C. § 1400(b) and 28 U.S.C. § 1391 because, among other things, each Defendant is *inter alia* incorporated in the State of Delaware and therefore "resides" in this judicial district and/or has committed acts of infringement in this District and has a regular and established place of business in this District. Those defendants that are foreign corporations not residing in any United States judicial district may be sued in any judicial district. 28 U.S.C. § 1391(c)(3). Moreover, the Defendants have litigated previous Hatch-Waxman patent infringement disputes in the District of Delaware.

GILENYA®

125. Novartis is the holder of New Drug Application ("NDA") No. 022527 by which the FDA granted approval for the commercial manufacturing, marketing, sale, and use of GILENYA® (fingolimod) Capsules, 0.5 mg. GILENYA® is the first in a new class of compounds known as sphingosine 1-phosphate receptor (S1PR) modulators. GILENYA® is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in patients 10 years of age and older. GILENYA® is the first oral drug that has been approved by the FDA for such an indication.

PRIOR GILENYA® LITIGATION WITH DEFENDANTS

126. Following receipt of each Defendant's Notice Letter, Novartis initiated suits for infringement of the '405 patent against each Defendant that are consolidated and still pending in this District, as described above. *Novartis Pharms. Corp. v. Accord Healthcare Inc., et al.*, C.A. No. 18-1043-KAJ (D. Del.).

127. Defendants Hetero, HEC, and Zydus opposed Novartis's motion for a preliminary injunction, seeking to engage in the commercial manufacture, use, offer to sell, or

sale of its ANDA Product, prior not only to the expiration of the '405 patent but to the conclusion of the above-described litigation. The Court granted Novartis's preliminary injunction motion on June 21, 2019. *See Novartis Pharms. Corp. v. Accord Healthcare Inc., et al.*, C.A. No. 18-1043-KAJ, D.I. 583 (D. Del. June 24, 2019).

128. Upon information and belief, each Defendant has made, and continues to make, substantial preparation to engage in the commercial manufacture, use, offer to sell, or sale of its ANDA Product, prior to the expiration of the '405 patent and imminently upon approval its ANDA.

129. The '405 patent expires on June 25, 2027, and has been granted a six-month pediatric regulatory extension to December 25, 2027.

THE PATENT-IN-SUIT AND GILENYA®

130. On January 28, 2020, the U.S. Patent and Trademark Office duly and legally issued the '179 patent, entitled "Dosage Regimen of an S1P Receptor Modulator." A true and correct copy of the '179 patent is attached hereto as **Exhibit A**.

131. The claims of the '179 patent are valid and enforceable. The '179 patent is wholly owned by Novartis, who therefore has the right to sue for and obtain equitable relief and damages for infringement of the '179 patent.

132. GILENYA® and the use of GILENYA® is covered by one or more claims of the '179 patent.

133. Novartis is filing the '179 patent for listing in FDA's official publication of approved drug products (the "Orange Book") in connection with GILENYA®, and expects FDA to so list the '179 patent in due course.

134. The '179 patent will expire on December 25, 2027.

COUNT I: INFRINGEMENT BY EACH DEFENDANT OF THE PATENT-IN-SUIT UNDER 35 U.S.C. 271(e)

135. Plaintiff incorporates each of the preceding paragraphs 1 – 134 as if fully set forth herein.

136. Each Defendant, or group of Defendants, by filing its ANDA, has necessarily represented to the FDA that, upon approval, its ANDA Product will have the same active ingredient, method of administration, dosage form, and dosage amount as GILENYA®, and will be bioequivalent to GILENYA®.

137. Each Defendant, or group of Defendants, via its Notice Letter and prior litigation conduct, has indicated its intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of its ANDA Product prior to the expiration of the '405 patent, and therefore prior to the expiration of the '179 patent.

138. Each Defendant's or group of Defendants ANDA submission seeking approval to engage in the commercial manufacture, use, offer to sell, or sale of its ANDA Product, prior to the expiration of the '179 patent constitutes infringement of one or more of the claims of the '179 patent under 35 U.S.C. § 271(e)(2)(A).

139. Upon information and belief, each Defendant or group of Defendants intends to engage in the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of its ANDA Product with the respective proposed labeling immediately and imminently upon final approval of its ANDA.

140. Upon information and belief, each ANDA Product's proposed labeling will be substantially identical to the GILENYA® label, and the GILENYA® label discloses all elements of at least claim 1 of the '179 patent. Specifically, the GILENYA® label instructs physicians to "[t]est patients for antibodies to varicella zoster virus (VZV) before initiating

GILENYA," and that "VZV vaccination of antibody-negative patients is recommended prior to commencing treatment with GILENYA." (Gilenya Label, Exhibit B, at 3.) The recommended dosing regimen of fingolimod is "0.5 mg orally once-daily" "for the treatment of relapsing forms of multiple sclerosis (MS), to include . . . relapsing-remitting disease." (*Id.* at 1.) Thus, upon information and belief, each ANDA Product labeling will disclose all elements of at least claim 1 of the '179 patent, therefore showing that use by, for example, patients and/or healthcare providers of each ANDA Product in accordance with its proposed labeling will infringe at least claim 1 of the '179 patent.

141. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of each ANDA Product would infringe one or more claims of the '179 patent.

142. Upon information and belief, use of each ANDA Product in accordance with and as directed by the respective proposed labeling for each ANDA Product would infringe one or more claims of the '179 patent.

143. Upon information and belief, each Defendant or group of Defendants will have actual knowledge of the '179 patent and will actively induce infringement of the '179 patent when its ANDA is approved, and will do so immediately and imminently upon final approval.

144. Upon information and belief, each Defendant or group of Defendants will know that its ANDA Product is especially made or adapted for use in infringing the '179 patent, and that each Defendant's ANDA Product is not suitable for any substantial non-infringing use. Upon information and belief, each Defendant or group of Defendants will contribute to the

infringement of the ’179 patent immediately and imminently upon approval of its respective ANDA.

145. The foregoing acts by each Defendant or group of Defendants constitutes and/or will constitute infringement of the ’179 patent, active inducement of infringement of the ’179 patent, and/or contribution to the infringement by others of the ’179 patent under 35 U.S.C. §§ 271(a)–(c).

146. If each Defendant’s infringement of the ’179 patent is not permanently enjoined, Plaintiff will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT II: DECLARATORY JUDGMENT OF INFRINGEMENT UNDER 35 U.S.C. 271(A), (B), OR (C)

147. Plaintiff incorporates each of the preceding paragraphs 1 – 146 as if fully set forth herein.

148. Upon information and belief, each Defendant or group of Defendants intends to engage in the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of its ANDA Product with the respective proposed labeling immediately and imminently upon final approval of its ANDA and prior to the expiration of the ’179 patent. Therefore a case or controversy exists between each Defendant or group of Defendants and Novartis as to infringement of the ’179 patent.

149. Upon information and belief, each ANDA Product’s proposed labeling will be substantially identical to the GILENYA® label, and the GILENYA® label discloses all elements of at least claim 1 of the ’179 patent. Specifically, the GILENYA® label instructs physicians to “[t]est patients for antibodies to varicella zoster virus (VZV) before initiating GILENYA,” and that “VZV vaccination of antibody-negative patients is recommended prior to

commencing treatment with GILENYA." (Gilenya Label, Exhibit B, at 3.) The recommended dosing regimen of fingolimod is "0.5 mg orally once-daily" "for the treatment of relapsing forms of multiple sclerosis (MS), to include . . . relapsing-remitting disease." (*Id.* at 1.) Thus, upon information and belief, each ANDA Product labeling will disclose all elements of at least claim 1 of the '179 patent, therefore showing that use by, for example, patients and/or healthcare providers of each ANDA Product in accordance with its proposed labeling will infringe at least claim 1 of the '179 patent.

150. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of each ANDA Product would infringe one or more claims of the '179 patent.

151. Upon information and belief, use of each ANDA Product in accordance with and as directed by the respective proposed labeling for each ANDA Product would infringe one or more claims of the '179 patent.

152. Upon information and belief, each Defendant or group of Defendants will have actual knowledge of the '179 patent and will actively induce infringement of the '179 patent when its ANDA is approved, and will do so immediately and imminently upon final approval.

153. Upon information and belief, each Defendant or group of Defendants will know that its ANDA Product is especially made or adapted for use in infringing the '179 patent, and that each Defendant's ANDA Product is not suitable for any substantial non-infringing use. Upon information and belief, each Defendant or group of Defendants will contribute to the infringement of the '179 patent immediately and imminently upon approval of its respective ANDA.

154. The foregoing acts by each Defendant or group of Defendants constitutes and/or will constitute infringement of the '179 patent, active inducement of infringement of the '179 patent, and/or contribution to the infringement by others of the '179 patent under 35 U.S.C. §§ 271(a)–(c).

155. If each Defendant's infringement of the '179 patent is not permanently enjoined, Plaintiff will suffer substantial and irreparable harm for which there is no remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Novartis prays that this Court grant the following relief:

1. A declaration that each Defendant's imminent making, using, offering to sell, or selling in the United States, or importing into the United States, or inducing or contributing to the same, of its ANDA Product will infringe the '179 patent.

2. A judgment that one or more claims of the '179 patent is not invalid, is enforceable, and is infringed by each Defendant's ANDA submission, and that each Defendant's making, using, offering to sell, or selling in the United States, or importing into the United States of its respective ANDA Product will infringe the '179 patent.

3. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of each Defendant's ANDA shall be a date not earlier than the expiration date of the '179 patent, including any extensions and/or additional periods of exclusivity to which Novartis is or becomes entitled.

4. An order enjoining each Defendant, its affiliates, subsidiaries, and each of their officers, agents, servants, and employees and those acting in privity or in concert with each Defendant, from making, using, offering to sell, or selling in the United States, or importing into

the United States its respective ANDA Product, until after the expiration date of the '179 patent, including any extensions and/or additional periods of exclusivity to which Novartis is or becomes entitled.

5. Damages, including monetary and other relief, to Novartis if any Defendant engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of its ANDA Product, prior to the expiration date of the '179 patent, including any extensions and/or additional periods of exclusivity to which Novartis is or becomes entitled.

6. Such further and other relief as this Court deems proper and just, including any appropriate relief under 35 U.S.C. § 285.

Dated: January 28, 2020

McCARTER & ENGLISH, LLP

By: /s/ Daniel M. Silver
Michael P. Kelly (#2295)
Daniel M. Silver (#4758)
Alexandra M. Joyce (#6423)
Renaissance Centre
405 N. King Street, 8th Floor
Wilmington, Delaware 19801
(302) 984-6300
mkelly@mccarter.com
dsilver@mccarter.com
ajoyce@mccarter.com

Attorneys Novartis Pharmaceuticals Corporation

OF COUNSEL:

Jane M. Love, Ph.D.
Robert W. Trenchard
Paul E. Torchia
Laura Corbin
GIBSON, DUNN & CRUTCHER LLP
200 Park Avenue
New York, New York 10166
(212) 351-4000
JLove@gibsondunn.com
RTrenchard@gibsondunn.com
PTorchia@gibsondunn.com
LCorbin@gibsondunn.com

Andrew P. Blythe
GIBSON, DUNN & CRUTCHER LLP
333 South Grand Avenue
Los Angeles, CA 90071
(213) 229-7000
ABlythe@gibsondunn.com

Christine L. Ranney
GIBSON, DUNN & CRUTCHER LLP
1801 California St.
Denver, CO 80202
(303) 298-5700
CRanney@gibsondunn.com